MEDICAL DEVICES MANAGEMENT SYSTEMS ISO 13485 CERTIFICATION QUESTIONNAIRE

PLEASE COMPLETE THIS QUESTIONNAIRE AND ATTACH ANY RELEVANT SUPPORTING INFORMATION DESCRIBING THE COMPANY'S MEDICAL DEVICES SYSTEM AND ACTIVITIES, e.g. COMPANY PUBLICITY MATERIAL. ON RECEIPT OF THE COMPLETED QUESTIONNAIRE A CUBE TIC LIMITED WILL PREPARE AND SUBMIT FOR YOUR APPROVAL A PROPOSAL DETAILING AUDIT OR TRANSFER COSTS AND TIMESCALES.

COMPANY NAME		
COMPANY ADDRESSES TO BE CERTIFIED (ADD MORE LINES IF REQUIRED)	Head Office:	
	Address 2:	
	Address 3:	
	Address 4:	
	Address 5:	

MULTISITE APPLICANTS: DOES EACH SITE FOLLOW A COMMON SYSTEM		TOTAL NUMBER OF SITES TO BE REGISTERED AS A MULTISITE	

CONTACT NAME		POSITION	
TELEPHONE		FAX	
E-MAIL		WEBSITE	
NAME OF CONSULTANT (IF USED)			
OTHER CERTIFICATIONS HELD			

TYPE OF APPLICATION (PLEASE SELECT FROM THE FOLLOWING OPTIONS)			
NEW ❑	RENEWAL ❑	TRANSFER ❑	SCOPE EXTENSION ❑
IF YOU ARE TRANSFERRING FROM ANOTHER CERTIFICATION BODY, PLEASE PROVIDE A COPY OF YOUR CURRENT ACCREDITED REGISTRATION CERTIFICATE AND YOUR TWO PREVIOUS CERTIFICATION BODY REPORTS			
Have you received Training or other services from A Cube TIC Limited in the preceding 2-year period- if YES please provide dates and detail of the service provided			

EMPLOYEES	TOTAL NUMBER OF STAFF	MANUFACTURING STAFF	SERVICE STAFF	STAFF WORKING OFF SITE	TOTAL STAFF AVAILABLE DURING THE AUDIT
FULL TIME					
PART TIME					
TEMPORARY					

SHIFT WORK (Y/N)		NUMBER OF SHIFTS		NUMBER OF PERSONNEL ON EACH SHIFT	

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PLEASE DESCRIBE THE GENERAL SCOPE OF YOUR BUSINESS ACTIVITY (SALES, MANUFACTURE, DESIGN AND MANUFACTRE, PROVISION OF SERVICES ETC) WHICH YOU INTEND TO INCLUDE WITHIN THE SCOPE OF REGISTRATION. IN ADDITION, CLEARLY DESCIBE THE DIVICES, COMPNENTS OR SERVICES PROVIDED. THE INFORMATION PROVIDED HERE WILL BE USED BY A CUBE TIC LIMITED (TRADING AS AJA EUROPE & A CUBE) TO DEFINE YOUR COMPANY'S SCOPE OF REGISTRATION					
DEVICE CLASSIFICATIONS (LOCAL)					
ARE THE DEVICES CE MARKED (Y/N)	YES❑	NO❑	ARE THE DEVICES UKCA MARKED?	YES❑	NO❑
ARE THEY PRIMARY DEVICES OR COMPONENT/SUB-ASSEMBLIES?					
COMPETENT AUTHORITY REGISTRATION NUMBER			NAME OF COMPETENT AUTHORITY		
ARE THE DEVICES EXPORTED TO, OR SOLD WITHIN THE EEC? (Y/N)	YES❑	NO❑	WHO IS YOUR APOINTED REPRESENTATIVE		
ARE THE DEVICES EXPORTED TO, OR SOLD WITHIN THE UK? (Y/N)	YES❑	NO❑	WHO IS YOUR APOINTED REPRESENTATIVE		
ARE YOU INTENDING TO SELF-DECLARE FOR CE AND/OR UKCA MARKING?					
IF YOU MANUFACTURE IVD DEVICES, WHAT CLASSIFICATION ARE THEY*					
**Manufacturers of IVD medical devices will have to comply with the requirements of the new European Regulation by 26 May 2022 in order to continue to place their devices on the European Union market.*					
IF YOU ARE A MANUFACTURER OF PARTS FOR USE IN MEDICAL DEVICES, OR YOU PROVIDE SUPPORT SERVICES, WHAT TYPE OF DEVICES ARE THESE PARTS OR SERVICES ASSOCIATED WITH? (INDICATE 'NOT KNOWN' IF YOUR CUSTOMERS DO NOT PROVIDE THIS INFORMATION)					
FINISHED MEDICAL DEVICE CATEGORY			*DETAILS OF EACH DEVICE*		
NON-ACTIVE MEDICAL DEVICES					
ACTIVE (NON-IMPLANTABLE) MEDICAL DEVICES					
ACTIVE IMPLANTABLE MEDICAL DEVICES					
IN VITRO DIAGNOSTIC MEDICAL DEVICES					
STERILISATION SERVICES					
CALIBRATION SERVICES			ACCREDITATION TO ISO 17025 IS MANDATORY		
ARE YOU PROVIDING A SUPPORT SERVICE SUCH AS CALIBRATION ETC. (Y/N)	YES❑	NO❑			
PLEASE DESCRIBE THE SERVICES PROVIDED BELOW					

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PLEASE PROVIDE DETAILS OF ANY PART OF YOUR COMPANY'S OVERALL ACTIVITY THAT IS OUTSOURCED TO OTHER ORGANISATIONS	
IF YOUR COMPANY CARRIES OUT WORK AT CUSTOMER SITES (SUCH AS INSTALATION AND COMMISSIONING), PLEASE PROVIDE DETAILS BELOW OF THE WORK CARRIED OUT BY YOUR COMPANY	TYPICAL NUMBER OF SITES OPERATING AT ANY TIME

PLEASE INDICATE ANY PERMISSABLE EXCLUSIONS FROM THE STANDARD THAT YOUR COMPANY HAVE NOMINATED.																								
6.1		6.2		6.3		6.4		7.1		7.2		7.3		7.4		7.5		7.6		8.1		8.2		8.3		8.4	

DO YOU CONSIDER THAT THE EXCLUSION OF ANY OF THESE CLAUSES WILL AFFECT YOUR ABILITY TO MEET CUSTOMER AND REGULATORY REQUIREMENTS Y/N?	YES❑	NO❑

PLEASE INDICATE ANY FURTHER CERTIFICATIONS YOUR COMPANY MAY BE INTERESTED IN									
ISO 9001		ISO 14001		ISO 45001		ISO 22000		ISO 27001	

PRIVACY

By signing this form, we declare that the data shown here are correct and complete. We also declare to have read the ACT information published on the Certification Body's website. The data provided will be processed for the purpose of technical / economic offer formulation.
I authorize A CUBE TIC LIMITED to process personal data for marketing, direct sales and market research purposes.

[] I give Consent [] I do not give consent

NAME		SIGNATURE	
POSITION		DATE OF COMPLETION	
EMAIL ADDRESS		PHONE NUMBER	

We inform you that, as a data subject, you have the right to withdraw your consent for one or more processing purposes at any time. This revocation, however, in no way affects the lawfulness of the processing carried out by us on the basis of the consent you have previously granted us.

PLEASE RETURN COMPLETED QUESTIONNAIRE TO A CUBE TIC Limited
OR TO YOUR LOCAL A CUBE TIC LIMITED's OFFICE

A CUBE TIC LIMITED: Unit 5, Middle Bridge Business Park, Bristol Road, Portishead, BS 20 6PN, UK
Tel: +44 - 01275 397423; E-mail: K.Bashar@acubetic.com

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AUDITOR CONFIRMATION (*A CUBE TIC LIMITED USES ONLY*)

TO BE COMPLETED BY THE APPOINTED A CUBE TIC LIMITED LEAD AUDITOR AT TIME OF THE STAGE 1 OR RECERTIFICATION/EXTENSION AUDIT ARISING FROM ENQUIRY AND PRESENTED WITHIN THE RELEVANT PACKAGE
I CONFIRM THAT THE INFORMATION AND DATA SHOWN ON THE COMPLETED QUESTIONNAIRE IS VALID AND ACCURATE TO THE COMPANY CIRCUMSTANCES SEEN AT THE TIME OF THE STAGE 1 AUDIT/RECERTIFICATION - *(Note – if any significant discrepancies between the information and data shown on the Questionnaire and those observed during the Stage 1 audit/ recertification are identified these must be brought to the attention of the company and to the attention of the A Cube TIC Limited's office Accreditation Review Officers immediately as these may impact the validity of the original proposal and contract as well as the adequacy of audit planning)*

Name		Signature		Date	